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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/721,857

11/25/2003

Fred H. Burbank

ETH5293USNP

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12/04/2008

Doherty IP Law Group LLC  
37 Belvidere Ave  
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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

12/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/721,857	<b>Applicant(s)</b> BURBANK ET AL.	
	<b>Examiner</b> ELIZABETH HOUSTON	<b>Art Unit</b> 3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8,12,15-18,21,22,32-34,36-41 and 43-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,12,15-18,21,22,32-34,36-41 and 43-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

A telephone interview with Mike Dougherty on 11/19/08 led to the determination that the refusal to enter the amended claims filed 09/29/08 was incorrect. As a result of this action, the claims are being entered. It has further been determined that the indication of allowable subject matter was in error and is being withdrawn based a new ground of rejection in view of newly applied prior art.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 12, 15-18, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Burbank (US 7,354,444).

3. Burbank discloses a device capable of occluding a female patient's uterine arteries with an unsymmetrical anatomy to treat a uterine disorder, comprising: a first occluding member and a second occluding member, each having a first elongated shaft (20), a first operative proximal shaft section (22) configured to extend out of the patient during treatment, which has a first distal shaft section (24) with a first pressure applying

occluding element (14) secured to the first distal shaft section, and a first mechanism/extending actuator (41) to distally extend at least part of the first pressure applying occluding element from a first position closer to the first operative proximal shaft section (as in fig. 1) to a second position further away from the first operative proximal shaft section (as in Fig. 8), wherein the first pressure applying occluding element includes an occlusion bar with a pressure applying surface (54 Fig. 3c) and a pair of legs (52 Fig. 3c) which extend from a surface opposite the pressure applying surface; and a connection (30) between the first and second occluding members which is configured to adjust spacing between the first and second pressure applying occluding elements to press the pressure applying occluding elements against the patient's vaginal wall to occlude underlying uterine arteries.

4. Regarding claim 2 the second occluding member has a second mechanism (41) to distally extend at least part of the second pressure applying occluding element from a first position (Fig. 8) closer to the second operative proximal shaft section to a second position (Fig. 9) further away from the second operative proximal shaft section.

Regarding claim 3 the connection between the first and second occluding members is a pivotal connection (30). Regarding claim 4, each of the proximal shaft sections of the occluding members includes a finger engaging grip (28). Regarding claim 5, at least part of the first pressure applying occluding element is configured for positional adjustment in-line with the first distal shaft section (Fig. 1). Regarding claim 6, at least part of the first pressure applying occluding element is configured for rotation within a plane at or near the first distal shaft section (via pivot (30)). Regarding claim 12, the first

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distal shaft section has a pair of arms (66) with recesses (72) therein configured to receive the legs extending from the occlusion bar. The first pressure applying occluding element is distally extendable about 0.25 to about 0.8 inch or up to about one inch from the first distal shaft section (depending on distance that shaft is removed after being separated). Regarding claims 15-18, the occluding elements are provided with blood flow sensors (18) that are Doppler crystal and has a direction of view away from the pressure applying surface (C11:L39-C12:L7).

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasson (US 5,562,680).

6. Hasson discloses an intravaginal device capable of occluding a female patient's uterine arteries with an unsymmetrical anatomy to treat a uterine disorder, comprising: a first occluding member having a first elongated shaft (14), a first operative proximal shaft section (88,90) configured to extend out of the patient during treatment, which has a first distal shaft section (18) with a first pressure applying occluding element (82) secured to the first distal shaft section (in that all the elements of the device are secured to each other), and a first mechanism/extending actuator (86, 92) to distally extend at least part of the first pressure applying occluding element from a first position closer to the first operative proximal shaft section to a second position further away from the first operative proximal shaft section and for moving the first pressure applying surface distally away from the distal end of the first elongated shaft (Fig. 7; C6:L6-18); wherein the first pressure applying element includes an occlusion bar with a pressure applying

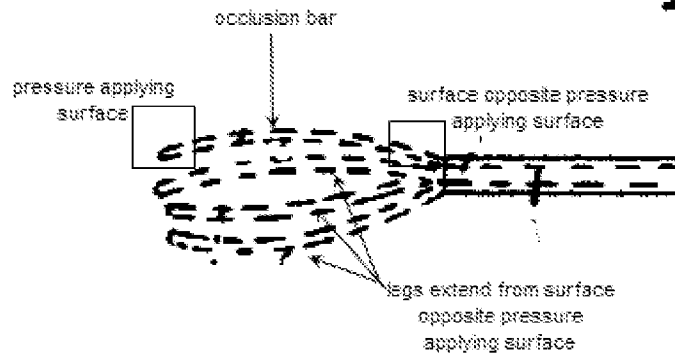
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surface and a pair of legs which extend from a surface opposite the pressure applying surface (see below); and a second occluding member (16) having a second elongated shaft, a second operative proximal shaft section configured to extend out of the patient during treatment and a second distal shaft section with a second pressure applying occluding element secured to the second distal shaft section; and a connection (46) between the first and second occluding members which is configured to adjust spacing between the first and second pressure applying occluding elements (C5: L13-20) to press the pressure applying occluding elements against the patient's vaginal wall to occlude underlying uterine arteries. Regarding claim 2 the second occluding member has a second mechanism to distally extend at least part of the second pressure applying occluding element from a first position closer to the second operative proximal shaft section to a second position further away from the second operative proximal shaft section (see Fig. 1 and above elements with respect to first occluding member).

Regarding claim 3 the connection between the first and second occluding members is a pivotal connection (Fig. 5 and 6; C5: L17). Regarding claim 4, each of the proximal shaft sections of the occluding members includes a finger engaging grip (C6:L10-15).

Regarding claim 5, at least part of the first pressure applying occluding element is configured for positional adjustment in-line with the first distal shaft section (Fig. 7).

Regarding claim 6, at least part of the first pressure applying occluding element is configured for rotation within a plane at or near the first distal shaft section (via pivot at connection (46) in Fig. 6).



### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 32-34, 36-41 and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank (US 7,354,444) in view of Holmes (US 6,716,218) and Hasson (US 4,944,741).

9. Burbank discloses the device as stated above including a second blood flow sensor and the first and second occluding elements being movable independently of one another along the longitudinal axis (prior to them being clamped together). Burbank does not disclose that the occluding element is pivotally connected to the distal shaft. However, Holmes discloses an instrument that similarly has a pair of shafts each having

a distal member (40) capable of occluding and that distally extends from away from the proximal shaft (note the pivotal connection between 36 and 14 and between 34 and 12 that will change the axial distance between 40 and handles); and a connection between the shafts. Holmes further discloses that the distal members (40) rotate by a pivotal connection to the distal shaft section (Fig. 3) in order to manipulate the distal end in such a way that provides optimal visualization as well as allowing optimum force to be applied (C2:L5-21).

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the additional feature of a pivotal connection to the occluding members of Burbank in order to allow the user to best locate the distal ends of the device. By allowing the user to rotate the distal ends, the user is able to accommodate many different shapes and sizes of anatomy with the added enhancement of allowing the surgeon to better visualize the area where pressure is applied. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention namely an occluding device that allows for the optimal maneuverability of the device for application to a variety of body types.

Burbank modified by Holmes does not disclose a rotating actuator for rotating the pressure applying surface. However Hasson discloses a first and second mechanism for rotating each of the distal ends of a surgical instrument (74 and 46). It would have



been obvious to one having ordinary skill in the art at the time of the invention to incorporate the rotating actuator into the modified device of Burbank and Holmes to replace the need for the surgeon to rotate the distal ends prior to use. The rotating actuator provides the user more freedom and greater range of motion while eliminating the need for guesswork by the surgeon by allowing rotation of the distal ends when the device is in the body. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 5,562,680) in view of Malecki (US 6,368,340).

11. Hasson discloses the invention substantially as claimed as stated above including a mechanism that extends the occlusion element distally away from the distal shaft section, but does not disclose that the mechanism for extending the occlusion element is effected by fluid under pressure.

12. Malecki discloses a clamp assembly that utilizes a hydraulic actuator for moving the occlusion element (C 20: L28-53). Malecki states that the use of a hydraulic system is an advantage because it does not take up much room in a trocar sleeve and enhances visualization (C 18: L 55-60).

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hydraulic system in place of the biasing springs into the

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invention of Hasson. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Furthermore, the hydraulic system is an enhancement over the mechanism used by Hasson for the reasons taught by Malecki and stated above.

13. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 5,562,680).

14. Schifano fails to particularly disclose that the occluding member is displaced a distance of up to about one inch of between 0.25 to 0.8 inch from the distal shaft section. However, it would have been obvious to displace the occluding member a varied distance of up to about one inch or between 0.25 to 0.8 inch from the distal shaft section in order to make the device of a sufficient size to be used to occlude uterine arteries. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

15. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasson (US 5,562,680) in view of Hossack et al (US 6,045,508).

16. Hasson discloses the invention substantially as claimed above but fails to disclose a blood flow sensor. However, Hossack teaches a Doppler crystal mounted in the surface of a device meant to be placed within the body (col. 3, lines 35-37 and col.

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4, lines 49-51). Therefore it would have been obvious to add the Doppler crystal of Hossack to the occlusion device of Hasson, in order to monitor blood flow to ensure that too much pressure is not being applied. Additionally, it would have been obvious to position the Doppler crystal so that it has a direction of view away from the pressure applying surface of the occluding element, so that the blood flow in the artery adjacent to the device can be measured.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731